

## **REMARKS**

### **I. Non-Final Action**

Applicant graciously thanks the Examiner for granting, during our phone conversation on June 15, 2007, Applicant's request to treat the April 20, 2007 Office Action as a Non-Final Office Action. During that conversation, the Examiner agreed that several of the rejections in the April 20, 2007 Office Action were new grounds of rejection that were neither necessitated by Applicant's amendment of the claims nor based on information submitted in an information disclosure statement. Thus, under MPEP § 706.07 (a), the Examiner agreed to allow Applicant to treat the April 20, 2007 Office Action as a Non-Final Office Action.

### **II. Claim Amendments**

Claim 106 has been amended to be consistent with claim 1, changing "a heteroatom" to "oxygen" and limiting the alkyl groups to 8 to 12 carbon atoms. Claims dependent on claims 1 and 106 have also been amended to correspond with these amendments. Thus, these amendments do not introduce new matter into the application.

New Claims 135 – 137 have been added to the application. Claims 135 and 136 depend from claims 105 and 123, respectively. The claims require that the compound (ii) listed in claims 105 and 123 is selected from the group consisting of polydimethylsiloxane having a chain length of from C<sub>12</sub> to C<sub>20</sub> and polydimethylhydrosiloxane having a chain length of from C<sub>12</sub> to C<sub>20</sub>. These claims are supported by at least paragraph 71 of the application and do not, therefore, introduce new matter into the application.

Claim 137 is a new claim that generally recites an anti-microbial composition consisting essentially of at least two anti-microbial agents, a compound having a low surface tension, and a polar solvent. The claim is supported in at least paragraphs 50, 69 – 74, and 71 – 72 of the application. Thus, the claim does not introduce new matter into the application.

In addition to the above, claims 47 - 49, 59, 108 - 110, and 114 have been canceled from the application.

### **III. Indefiniteness Rejections under 35 U.S.C. § 112**

The Examiner rejected claims 62, 70, 71, 89, 96, 99, and 106 under 35 U.S.C. § 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as his invention. Specifically, the Examiner asserts that claims 62, 70, and 71 lack antecedent basis for the limitation “the at least one anti-microbial agent is selected from an amphoteric compound, an iodophore, . . . and a nitrogen based heterocyclic compound.” The Examiner asserts that the claim broadens the scope of the anti-microbial agent in claim 1 for which there exists no antecedent basis.

Amended claim 1 of the application recites “An anti-microbial composition consisting essentially of: (i) at least one anti-microbial agent, wherein at least one of the anti-microbial agents is an anti-microbial agent having a high surface tension . . .” Amended Claim 62 and claims 70 and 71, which depend from claim 62, simply state that at least one of the anti-microbial agents of claim 1 “is selected from an amphoteric compound, an iodophore, . . . and a nitrogen based heterocyclic compound.” Thus, antecedent basis does exist for claims 62, 70, and 71, and the claims do not broaden

the scope of claim 1 at all.

The Examiner next asserted that claims 89, 96, and 125 lack sufficient antecedent basis for the limitation “the functional compound.” Claims 89 and 125 have been amended to change the word “compound” to “material”, consistent with the language used in claims 88 and 124, the claims from which they depend. Accordingly, the amended claims have proper antecedent basis and should not be considered indefinite.

The Examiner asserted that claim 99 lacks proper antecedent basis for the limitation “adding the at least one compound”. Claim 99 depends from claim 1, which recites, in part: “(ii) a compound having a low surface tension of from 8 to 14 mN/m, and selected from the group consisting of silanes, soya lecithins, polydimethylsiloxanes, and polydimethylhydroxysiloxanes.” Amended claim 99 recites: “A method of manufacturing an anti-microbial composition according to Claim 1, the method comprising the steps of (a) mixing the anti-microbial agents together, (b) adding the compound (ii) to the anti-microbial agents, (c) adding the polar solvent to the mixture of the compound (ii) and anti-microbial agents and (d) agitating the resulting mixture until a clear solution is formed.” It is clear that the phrase “adding the compound (ii)” in claim 99 refers to the limitation in claim 1 of “(ii) a compound having a low surface tension of from 8 to 14 mN/m, and selected from the group consisting of silanes, soya lecithins, polydimethylsiloxanes, and polydimethylhydroxysiloxanes.” Thus, proper antecedent basis exists for the claim and the claim should not be considered indefinite.

Claim 106 was rejected as indefinite based upon the phrase “first anti-microbial agent” being confusing because the claim does not refer to a second or additional anti-

microbial agent. The claim has been amended to delete the word “first”. Claim 1 of the application and claims depending from claims 1 or 106 have been amended to be consistent therewith. Based upon the above amendments and arguments, Applicant respectfully requests that the indefiniteness rejections be withdrawn.

#### **IV. Lack of Enablement Rejection under 35 U.S.C. § 112**

The Examiner rejected the claims under 35 U.S.C. § 112 as lacking enablement “for an anti-microbial agent comprising a quaternary ammonium compound having the general formula in which one or two of the R groups alkyl substituted by aryl or interrupted by aryl or heteroatom (oxygen) and the other R groups being C<sub>1</sub> to C<sub>4</sub> alkyl groups or an aryl ring substituted benzalkonium halide plus at least one compound selected from silanes, soya lecithins, polydimethylsiloxanes, polydimethylhydroxy-siloxanes and mixtures thereof.” April 20, 2007 Office Action, page 3 – 4. The Examiner notes that “Applicant’s Annex I and Annex II do not support a combination of a quaternary ammonium compound having the general formula R<sup>1</sup>R<sup>2</sup>R<sup>3</sup>R<sup>4</sup>N<sup>+</sup>X<sup>-</sup> in which one or two of the R groups alkyl substituted by aryl or interrupted by aryl or heteroatom (oxygen) and the other R groups being C<sub>1</sub> to C<sub>4</sub> alkyl groups or an aryl ring substituted benzalkonium halide plus at least one compound selected from silanes, soya lecithins, polydimethylsiloxanes, polydimethylhydroxy-siloxanes and mixtures thereof.” April 20, 2007 Office Action, page 4.

The Examiner has not established a *prima facie* case of lack of enablement. As stated by the Federal Circuit:

When rejecting a claim under the enablement requirement of Section 112, the [Examiner] bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection

provided by the claim is not adequately enabled by the description of the invention provided in the specification of the application.

*In re Wright*, 999 F.2d 1557, 27 USPQ 2d 1510, 1513 (Fed. Cir. 1993) (emphasis added). Because the Examiner has not provided any explanation as to why or how the claims are not enabled by the specification, a *prima facie* case of enablement has not been presented. The declarations submitted by Applicant, such as Annex I and II, are irrelevant to an enablement analysis.

Further, even if the Examiner had presented a *prima facie* case of lack of enablement, such rejection can be overcome with reference to the specification itself. In considering enablement of an invention, “[t]he specification need describe the invention only in such detail as to enable a person skilled in the most relevant art to make and use it.” *In re Naquin*, 398 F.2d 863, 158 USPQ 317, 319 (C.C.P.A. 1971).

Paragraph 31 sets forth that the invention comprises a first compound having a high surface tension, a second compound having a low surface tension, an anti-microbial agent, and a polar solvent.

Paragraph 47 of the application discloses that the first compound can be a second anti-microbial agent. Paragraph 54 of the application discloses that the second anti-microbial agent can be a quaternary ammonium compound. Paragraph 56 sets forth that the quaternary ammonium compound may have “the general formula  $R^1R^2R^3R^4N^+X^-$ , in which one or two of the R groups are alkyl substituted by aryl or interrupted by aryl or a heteroatom, such as oxygen, and the other R groups are the same or different and are C<sub>1</sub> to C<sub>4</sub> alkyl groups.” Paragraph 57 of the application sets forth that the quaternary ammonium compound may be an “aryl ring substituted

benzalkonium halide.” Thus, the quaternary ammonium compound itself is fully disclosed and enabled in the specification.

Paragraphs 71 and 72 describe the use of a second compound selected from the group consisting of silanes, soya lecithins, polydimethylsiloxanes, and polydimethylhydroxysiloxanes. Thus, the use of this second compound is fully disclosed and enabled in the specification. Based upon at least paragraph 31, the combination of a first compound, which can be a quaternary ammonium compound as claimed, and a second compound, which can be selected from the claimed compounds, is clearly described and enabled in the specification. The specification describes the invention in such detail as to enable a person skilled in the most relevant art to make and use it. Accordingly, Applicant respectfully requests that the enablement rejection be withdrawn.

**V. Rejection under 35 U.S.C. § 103(a)**

The Examiner rejected of the claims under 35 U.S.C. § 103(a) as being unpatentable as obvious over Trinh, *et al.* Applicant respectfully submits that the amended claims are not obvious in light of this reference because Trihn fails to teach or suggest all of the claim elements.

The Examiner asserts that the composition of Trihn “can comprise dimethyl polysiloxanes (hydrophobic) and an antimicrobial active,” citing Col. 9, lines 47 – Col. 13, line 38, but especially Col. 11, line 48 – Col. 12, line 63. April 20, 2007 Office Action, page 5. The Examiner is mistaken in this assertion.

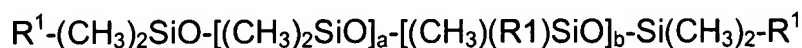
Trihn actually teaches the use of “polyalkylene oxide polysiloxanes having a dimethyl polysiloxane hydrophobic moiety and one or more hydrophilic polyalkylene

side chains.” Col. 11, lines 48 – 51. Thus, Trihn teaches a compound having a dimethyl polysiloxane moiety, but does not teach or suggest the use of polydimethylsiloxane itself.

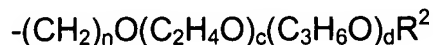
Polydimethylsiloxanes, as used in the present invention, have the following formula:



Polyalkylene oxide polysiloxanes, as described in Trihn, however, have the formula:



wherein a+b are from about 1 to about 50, preferably from about 3 to about 30, more preferably from about 10 to about 25, and each R<sup>1</sup> is the same or different and is selected from the group consisting of methyl and a poly(ethyleneoxide/propyleneoxide) copolymer group having the general formula:



with at least one R<sup>1</sup> being a poly(ethyleneoxide/propyleneoxide) copolymer group, and wherein n is 3 or 4, preferably 3; total c (for all polyalkyleneoxy side groups) has a value of from 1 to about 100, preferably from about 6 to about 100; total d is from 0 to about 14, preferably from 0 to about 3; and more preferably d is 0; total c+d has a value of from about 5 to about 150, preferably from about 9 to about 100 and each R<sup>2</sup> is the same or different and is selected from the group consisting of hydrogen, an alkyl having 1 to 4 carbon atoms, and an acetyl group, preferably hydrogen and methyl group. Each polyalkylene oxide polysiloxane has at least one R<sup>1</sup> group being a poly(ethyleneoxide/propyleneoxide) copolymer group.

Col. 11, lines 48 – Col. 12, line 10.

Thus, it is clear that the surfactant taught in Trihn is very different in structure from the polydimethylsiloxanes of the present invention. The polyalkylene oxide polysiloxane of Trihn also has significantly different properties than the

polydimethylsiloxanes used in the present invention. For example, the polyalkylene of Trihn comprises both hydrophobic and hydrophilic moieties while the polydimethylsiloxanes of the present invention are entirely hydrophobic. Thus use of these very different materials will produce compositions with very different properties. Because Trihn fails to teach or suggest the use of a polydimethylsiloxane, the reference is not persuasive in an obviousness analysis and the Examiner has failed to establish a *prima facie* case.

The Examiner noted on page 5 of the Office Action that “the simple act of combining and mixing ingredients is common in this art therefore the method of making the composition as described in claim 99 is not patentable.” Applicant points out that claim 99 is actually dependent on claim 1. Thus, if claim 1 is allowable, which Applicant believes it is, claim 99 should also be allowable. Additionally, the Examiner has not provided any evidence that combining and mixing these specific ingredients in this specific manner is known in the art. Thus, the Examiner has not established a *prima facie* case that claim 99 of the application is obvious.

In view of the foregoing arguments, we respectfully submit that the rejected claims are patentably distinct over the reference cited by the Examiner and meet all other statutory requirements. We believe that the present Application is now in complete condition for allowance and, therefore, respectfully request the Examiner to reconsider the rejections in the Office Action and allow this Application.

We invite the Examiner to telephone the undersigned should any issues remain after the consideration of this response. Please charge any additional fees that may be required to Deposit Account No. 50-2548.



Respectfully requested,

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